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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/214,277	03/01/1999	KENJI KAWADA	32-248P	8984

7590 11/02/2004

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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/214,277	KAWADA ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34,35,37,40,42-49 and 52-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34,35,37,40,42-49 and 52-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response filed on 10/14/2004 under 37 CFR 1.116 in reply to the final rejection has been considered and made of record. Claims 60-73 have been rejoined.

Claims 34-35, 37, 40, 42-49 and 52-73 are now pending.

In view of applicants' response, the 112 first paragraph new matter rejection made over claims 42-44 and 53-54 in the previous office action has been obviated.

Upon further consideration, the Finality of the previous office action is withdrawn to apply new rejections as shown below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34-35, 37, 40, 42-49 and 52-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making salts of the claimed compounds, does not reasonably provide enablement for making hydrate of the claimed compounds. The specification does not enable any person skilled iii the art of synthetic organic chemistry to make the invention commensurate in scope with these claims. Following apply.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence

or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The factors to be considered in making an enablement rejection have been summarized above. In the present case the important factors leading to a conclusion of undue experimentation are the absence of any working example of a formed solvate, the lack of predictability in the art, and the broad scope of the claims.

There is no working example of any hydrate formed. The claims are drawn to hydrate, yet the numerous examples, which show process of making nearly 2500 compounds, presented in specification pages 49- 452, all failed to produce a hydrate. Thus a hydrate cannot be simply willed into existence by dissolving a compound in water or solvent containing water as evident from the numerous examples. As was stated in Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there, is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ...' no evidence that such compounds even exist." The same circumstance appears to be true here. Instant compound claims embrace hundreds of thousands of compounds and specification exemplifies nearly 2500 compounds, none of which is shown to form a hydrate. Although use of water and organic solvents a re taught in the process of making, it does not result in a hydrate or a solvate. Thus a solvate or hydrate cannot be willed into existence by use water and or solvents and specification clearly lacks in teaching or suggestion how to form a hydrate despite the

lack of hydrate formation with the exemplified compounds. Although one trained in the art would know how to form a salt based on the structural-makeup of the compounds particularly due to at least presence of phenolic hydroxyl, there is no such feature known to suggest that these compounds would form a hydrate. There is no evidence that hydrates of these compounds actually exists; if they did, they would have formed. Hence, applicants must show that hydrates can be made, or limit the claims accordingly.

g) The state of the art is that is not predictable whether solvates will form. As noted above, there are no known criteria that would suggest what compounds form hydrate. In the realm of physical chemistry, a solvate of organic molecule is an interstitial solid solution. This phrase is defined in the second paragraph on page 358 of West (Solid State Chemistry). The solvent molecule is a species introduced into the crystal and no part of the organic host molecule is left out or replaced. In the first paragraph on page 365, West (Solid State Chemistry) says, "it is not usually possible to predict whether solid solutions will form, or if they do form what is the compositional extent". Thus, in the absence of experimentation one cannot predict if a particular solvent will solvate any particular crystal. In the instant case of hydrate a similar reasoning apply. Although there are number of structurally related compounds disclosed in the prior art of record including those cited in the Information Disclosure Statements, none of these compounds are shown to form hydrate. Thus, one trained in the art cannot get any guidance as to how to form hydrate with the instant compounds.

h) The breadth of the claims includes all of the hundreds of thousands of compounds of formula. (I). For examples, with 10 R groups each having at least 26 choices, three X choices and at least 11 Y choices, the instant compounds would be 26 X 26 X 26 X 26 X 26 X 26 X 26 X 26 X 26 X 3 X 11 = 4658514156561408 compound! Again this is a conservative estimate as optional substituents are excluded. Thus, the scope of instant compounds claims is extremely broad. One trained in the art therefore do extensive and undue experimentation to see whether instant compounds would form a hydrate and if so which of these compounds would do so. This clearly calls for undue experimentation.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case. In view of the breadth of the claims, the chemical nature of the invention, the unpredictability of solvate formation in general and hydrate formation in particular, and the lack of working examples regarding the hydrate of the claimed compounds embraced in the instant claims, one having ordinary skill in the art would have to undergo an undue amount of experimentation to make the instantly claimed invention commensurate in scope with the claims.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is

clearly justified here. Thus, undue experimentation will be required to make Applicants' invention.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (571) 272-0674. If Applicants are unable to reach Mukund Shah within 24-hour period, they may contact James O. Wilson, Acting-SPE of art unit 1624 at 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Venkataraman Balasubramanian

Venkataraman Balasubramanian

10/28/2004